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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WEGERT, SANDRA L	

ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No.	Applicant(s)	
	09/866,066	BENJAMIN ET AL.	
	Examiner	Art Unit	
	Sandra Wegert	1647	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-115* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-115* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-29, 47, 62(a), 66-68, 76-88, 102 and 107(a), drawn to *ion-x* nucleic acids, complementary nucleic acids, nucleic acid constructs, host cells comprising and recombinant production of proteins, classified in class 435, subclass 69.1+.

II. Claims 30-35, 74, 75 and 89-94, drawn to an *ion-x* polypeptide, classified in class 530, subclass 350+.

III. Claims 36-38 and 95-97, drawn to an antibody against *ion-x* and methods of making an antibody, classified in class 530, subclass 387.1+.

IV. Claims 40-43, 50, 70, 72, 73 and 98-99, drawn to a method of identifying a compound that binds *ion-x,* classified in class 435, subclass 35+.

V. Claims 44 and 100, drawn to a compound, such as an antagonist, that binds *ion-x* but does not transduce a signal, classification dependent on structure of recited compound.

VI. Claims 45, 46, 54 and 101, drawn to a method of identifying a compound that binds the polynucleotide encoding *ion-x,* classified in class 514, subclass 44+.

VII. Claims 48, 49, 51, 69, 103, 104, 111, 112, 114 and 115, drawn to a method of identifying a compound that modulates the activity of *ion-x,* classification dependent on structure of recited compound.

VIII. Claims 52 and 105, drawn to a compound, such as an agonist, that modulates the activity of *ion-x*, classification dependent on structure of recited compound.

IX. Claims 53 and 55, drawn to a method of identifying an animal homologue of *ion-x*, using computer software, classified in class 702, subclass 20+.

X. Claims 56-61 and 106, drawn to a method of screening human subjects for disorders related to *ion-x*, classified in class 435, subclass 69.1+.

XI. Claim 62(b), and 107(b), drawn to storage media containing information for identifying polymorphisms related to *ion-x*, classified in class 702, subclass 20+.

XII. Claims 63 and 108, drawn to a method of identifying an *ion-x* allelic variant, classified in class 536, subclass 24.31+.

XIII. Claims 64, 65, 109 and 110, drawn to an *ion-x* allelic variant, classified in class 536, subclass 23.1+.

XIV. Claims 71-73 and 113-115, drawn to a method for identifying a modulator of binding between *ion-x* and a ligand, classified in class 435, subclass 35+.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for Inventive Groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons: Groups I, II, III, V, VIII, XI and XIII, are independent and distinct, each from the other, because they comprise products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. The nucleic acid of group I can be used to make a hybridization

probe or can be used in gene therapy as well as in the production of the protein of interest. The polypeptide of invention II can be used to make the antibodies, as well as to search for a ligand. The antibody of Invention III can be used for immunoprecipitation of the proteins of interest as well as in-situ localization. With regards to Inventions V and VIII, agonists and antagonists necessarily have different structures and are used for different purposes. The storage media of Group XI can be used to store any information, besides genetic sequences and software and is not made of biological material. The DNA of Group XIII can be used to study normal variation of the gene across a population.

Additionally, Groups I and II are related as process of making and product made. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product, or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05 (f)). In the instant case the polypeptide can be prepared by materially different processes, such as by chemical synthesis, or obtained from nature using various isolation and purification protocols.

Invention I is unrelated to Inventions IV, V, VII, IX and XIV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotide of Group I is neither used in nor produced by any of the methods of Groups IV, V, VII, IX and XIV.

Inventions I is related to Inventions VI, X and XII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the polynucleotide of Group I can be used to synthesize the polypeptides of Group II, as well as in gene therapy.

Invention II is related to Inventions IV and VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the polypeptide of Group II can be used to generate antibodies as well as to search for ligands.

Invention II is unrelated to Inventions VI, IX, X and XII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide of Group II is neither used in nor produced by any of Groups VI, IX, X and XII.

Invention II is related to Invention XIV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the polypeptide of Group II has many uses, such as in a therapeutic composition and to raise antibodies. Likewise, the method of searching for a binding partner of the ligand of *ion-x* (for example, a chelator) does not necessarily require the *ion-x* receptor polypeptide.

Invention III is unrelated to Inventions IV, VI, VII, IX, X, XII and XIV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody of Group III is neither used in nor produced by any of Groups IV, VI, VII, IX, X, XII and XIV.

Group IV is related to Group V as process of searching for a ligand and the ligand detected. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to find other and materially different product, or (2) that the product as claimed can be detected by another and materially different process (MPEP § 806.05 (f)). In the instant case the binding assays listed can be used for purposes other than to find a ligand for a receptor.

The methods of Inventions I, IV, VI, VII, IX, X, XII and XIV are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

Group IV is related to Group VIII as a process of searching for a ligand and the ligand detected. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to find other and materially different product, or (2) that the product as claimed can be detected by another and materially different process (MPEP § 806.05 (f)). In the instant case the binding assays listed can be used for purposes other than to find a ligand for a receptor.

Invention IV is unrelated to Inventions XI and XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the DNA and storage media are neither used in nor produced by the method of Invention IV.

Invention V is unrelated to Invention VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods used to find a polynucleotide that binds to the DNA encoding *ion-x* is unrelated to a ligand of *ion-x*.

Group V may be related to Group VII as process of searching for a binding partner and the binding partner detected. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to find other and materially different product, or (2) that the product as claimed can be detected by another and materially different process (MPEP § 806.05 (f)). In the instant case the binding assays listed can be used for purposes other than to find a binding partner for *ion-x*.

Invention V is unrelated to Inventions IX, X and XII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antagonist of Invention V is neither used in nor produced by any of the methods of Groups IX, X and XII.

Invention V is related to Invention XIV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the ligand of Group V has many uses besides searching for a chelator.

Invention VI is unrelated to Inventions VIII and XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the ligand and storage media are neither used in nor produced by the method of Invention VI.

Group VI may be related to Group XIII as process of searching for a binding partner and the binding partner detected. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to find other and materially different product, or (2) that the product as claimed can be detected by another and materially different process (MPEP § 806.05 (f)). In the instant case the assays used to detect complementary DNA can be used to bind antisense in addition to a variant DNA.

Group VII is related to Group VIII as process of searching for a binding partner and the binding partner detected. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to find other and materially different product, or (2) that the product as claimed can be detected by another and materially different process (MPEP § 806.05 (f)). In the instant case an assay used to detect an agonist of *ion-x,* such as

patch-clamping, or a second messenger assay can be used to find many agonists of many receptors.

Invention VII is unrelated to Inventions XI and XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the storage medium of Invention XI and the DNA of Invention VIII are neither used in nor produced by the methods of Group VII.

Inventions VIII is unrelated to Inventions IX, X and XII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the agonist of Group VIII is neither used in nor produced by any of the methods of Inventions IX, X and XII.

Group VIII may be related to Invention XIV as a process of searching for a binding partner and the binding partner detected. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to find other and materially different product, or (2) that the product as claimed can be detected by another and materially different process (MPEP § 806.05 (f)). In the instant case binding assays can be used for purposes other than to find a binding partner for *ion-x*.

Invention IX is unrelated to Inventions XI and XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP

§ 808.01). In the instant case the storage media of Group XI and the gene of Invention XIII are neither used in nor produced by the methods of Invention IX.

Invention X is unrelated to Inventions XI and XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the storage media of Group XI and the gene of Invention XIII are neither used in nor produced by the methods of Invention X.

Invention XI is unrelated to Inventions XII and XIV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the storage media of Group XI is neither used in nor produced by the methods of Groups XII and XIV.

Group XII is related to Invention XIII as a process of searching for a product and the product detected. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to find other and materially different product, or (2) that the product as claimed can be detected by another and materially different process (MPEP § 806.05 (f)). In the instant case the methods used to find an allelic variant can be used to find any DNA.

Invention XIII is unrelated to Invention XIV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP §

808.01). In the instant case the DNA of Invention XIII is neither used in nor produced by the methods of Group XIV.

Because these inventions are distinct for the reasons given above and the search required for each group is unique, as well as by their different classifications, divergent subject matter and different search requirements, restriction for examination purposes as indicated is proper.

Furthermore, a secondary restriction is required under 35 USC 121 as follows:

For Inventive Groups I-XIV, it is required that applicant elect:

A) One sequence from the following:

SEQ ID NO: 1-42.

Each amino acid or nucleotide sequence above is independent and distinct, each from the other, because each has an independent and distinct chemical structure. Their searches are non-overlapping, resulting in an undue search burden.

Furthermore, a secondary restriction is required under 35 USC 121 as follows:

For Inventive Group IV, it is required that applicant elect:

B) One protein binding assay from the following:

a) a gel shift assay,

b) a Western blot

c) radiolabelled competition assay,

d) phage-based expression cloning,

e) co-fractionation by chromatography,

f) co-precipitation,

g) cross-linking,

h) interaction trap/two hybrid analysis,

i) southwestern analysis, or

j) an ELISA.

The methods of Inventions a)-j) are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

In response to this requirement, applicants must elect from Groups I through XIV, and a SEQ ID NO. If Applicant elects Invention IV, he/she must also elect an assay method. Applicant is advised that in order for the reply to this requirement to be complete it must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 8:30 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW

October 1, 2002

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER